Remarks

Objection to Claim 39

Claim 39 is amended to recite "SEQ ID NO:3" rather than "SEQ ID: 3." This amendment does not add new matter or require a new search.

Rejections Under 35 U.S.C. § 112 ¶ 1

Claims 1, 2 and 135-138 remain rejected under 35 U.S.C. § 112 ¶ 1 as failing to comply with the written description requirement and as not being enabled. Applicants respectfully traverse these rejections.

The Final Office Action asserts that the specification neither describes nor enables the full scope of "sphingosine kinase 1 (SPHK1) human gene copy number" as recited in independent claim 1. Final Office Action at pages 3 and 10.

Scope of claims 1, 2, and 135-138

First, the Examiner ignored the fundamental rule of claim construction that every limitation is material and that what is claimed is what is defined by the claim as a whole. *General Foods Corp. v. Studiengesellschaft Kohle GmbH*, 972 F.2d 1272, 1280, 23 U.S.P.Q.2d 1839, 1345 (Fed. Cir. 1992). By its plain language, independent claim 1 involves determining the copy number of human SPHK1 genes in samples taken from human tissue; *i.e.*, SPHK1 genes which naturally occur in human tissues. No interspecies homologs exist in human tissue and hence none are encompassed within the claims.

Second, the Examiner relied on page 66 (apparently lines 5-22) of the specification as support for the assertion that the scope of the recited human SPHK1 gene is overly broad. It is improper to import a broad definition from the specification into a claim. M.P.E.P. § 2111.01.

Claims 1, 2, and 135-138 encompasses only human SPHK1 genes. Moreover, even page 66, lines 5-22 of the specification does not support the Examiner's construction of the human SPHK1 gene. That portion of the specification states that "[t]he term SPHK1 ***can*** refer to" a variety of items, including "protein (or polypeptide)." Specification at page 66, lines 1-2, emphasis added. There is no protein or polypeptide recited in claim 1. Further, while the specification notes that "SPHK1 polynucleotides or polypeptides are typically from a mammal including, but not limited to human, rat, mouse, hamster, cow, pig, horse, sheep, or any mammal," specification at page 66, lines 1-21, independent claim 1 does not recite the SPHK1 gene from rat, mouse, hamster, cow, pig, horse, sheep or "any mammal." Independent claim 1 recites determining sphingosine kinase 1 (SPHK1) human gene copy number in a test sample from a region of a human. Because the plain language of the claim clearly limits the recited SPHK1 gene to human SPHK1 genes, claims 1, 2, and 135-138 cannot be read as broadly as the Examiner contends.

Written Description

The Examiner has not set forth express findings of fact to support a *prima facie* case of lack of written description as required by M.P.E.P. § 2163.04. With respect to the human SPHK1 gene, the Examiner sets forth no evidence that the genus is so varied that the specification does not describe it. The Final Office Action provides no reasons at all why, in view of the disclosure of the application as filed, a person skilled in the art at the application's priority date would not have recognized that the inventors possessed the invention of claims 1, 2, and 135-138. In fact, the evidence is to the contrary. A specification adequately describes a genus to the skilled artisan if it permits the artisan to "visualize or recognize members of the

genus." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). The naturally occurring human SPHK1 gene was well known in the art at the priority date of this application. *See, e.g.*, the GenBank entry for NM_021972, which was provided with the Final Office Action. An adequate written description of a gene which is well known in the art does not require a structural recitation either in the specification or in the claims. *See Capon v. Eshhar*, 418 F.3d 1349, 1360-61, 76 U.S.P.Q.2d 1078, 1087 (Fed. Cir. 2005) ("the Board erred in ruling that § 112 imposes a *per se* rule requiring recitation in the specification of the nucleotide sequence of claimed DNA, when that sequence is already known in the field."). Thus, the fact that the claims do not recite a sequence identifier does not mean that the claims lack written description. Under *Capon*, a sequence identifier is not required to describe the human SPHK1 gene.

Enablement

The enablement rejection, too is based on the Examiner's overly broad construction of the claims' recitation of a human sphingosine kinase 1 gene. The Examiner refers to page 66 of the specification and contends that "the specification provides an almost limitless breadth to the nucleic acid sequences encompassed by the term SPHK1." Final Office Action at page 9. This assertion is countered above in connection with the rebuttal of the written description rejection. There is no legal or factual basis for concluding it would require undue experimentation to practice the method of claims 1, 2, and 135-138. The specification supplies the skilled artisan with the sequence set forth in SEQ ID NO:1. Using primers and probes based on SEQ ID NO:1, the skilled artisan can readily determine SPHK1 gene copy number in human tissue.

Please withdraw the rejections.

Rejection Under 35 U.S.C. § 102(b)

The Final Office Action rejects claims 1 and 2 under 35 U.S.C. § 102(b) as anticipated by Michelland.[1] Applicants respectfully traverse the rejection.

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The Final Office Action contends that Michelland teaches analysis of chromosomal gain of a region of chromosome 17q that includes the SPHK1 gene. Final Office Action at page 15. In effect, the Examiner argues that disclosure of a genus (amplification of genes in the 17q25-ter region) anticipates a species (amplification of SPHK1). This is not the law. See *In re Meyer*, 599 F.2d 1026, 1031, 202 U.S.P.Q. 175, 179 (C.C.P.A. 1979) ("The genus, 'alkaline chlorine or bromine solution,' does not identically disclose or describe, within the meaning of § 102, the species alkali metal hypochlorite, since the genus would include an untold number of species.").

Michelland does not expressly or inherently teach determining SPHK1 gene copy number or that a detectable amplification of the SPHK1 gene in a test sample relative to a control suggests the presence of a precancerous lesion or a cancer in a human. Michelland therefore does not anticipate claims 1 or 2.

Please withdraw the rejection.

[1] Michelland *et al.*, *Cancer Genet. Cytogenet. 114*, 22-30, 1999.

Rejection Under 35 U.S.C. § 103(a)

The Final Office Action rejects claims 135-144 under 35 U.S.C. § 103(a) as obvious over Michelland. Applicants respectfully traverse the rejection.

The U.S. Patent and Trademark Office bears the initial burden of establishing a *prima facie* case of obviousness. The *prima facie* case requires three elements:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

M.P.E.P., 8th ed., § 2142. As noted above, Michelland does not expressly or inherently teach determining SPHK1 gene copy number or that a detectable amplification of the SPHK1 gene in a test sample relative to a control suggests the presence of a precancerous lesion or a cancer in a human. Inherency has no place in an obviousness rejection; inherency and obviousness are separate concepts, and "that which may be inherent is not necessarily known." *In re Spormann and Heinke*, 150 U.S.P.Q. 449, 452 (C.C.P.A. 1966). The law is clear that an obviousness rejection cannot be based on what is unknown. *Id.* On the contrary, an obviousness determination must be based on what is known, as is clear from the Supreme Court's fact-based *Graham* test for determining obviousness.

The Final Office Action has not established a *prima facie* case of obviousness based on Michelland. Please withdraw the rejection.

Respectfully submitted,

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